

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA  
AT CLARKSBURG**

**BIOGEN INTERNATIONAL GMBH  
and BIOGEN MA INC.,**

**Plaintiffs,**

**v.**

**MYLAN PHARMACEUTICALS INC.,**

**Defendant.**

**Civil Action No. 1:17-cv-116-IMK**

**FILED UNDER SEAL**

**DEFENDANT’S MOTION FOR LEAVE TO FILE REPLY  
IN SUPPORT OF MOTION IN LIMINE TO  
EXCLUDE UNDISCLOSED INVALIDITY THEORY (DKT. NO. 301)**

Defendant, Mylan Pharmaceuticals Inc. (“Mylan”), moves for leave to file a reply brief in support of “Mylan Pharmaceuticals Inc.’s Motion *in Limine* to Exclude Undisclosed Theory to Rebut Invalidity” (Dkt. No. 301). The Court’s scheduling order does not provide for reply briefs with regard to motions *in limine*. The response brief of Biogen<sup>1</sup> (Dkt. No. 314), however, makes erroneous claims and arguments that Mylan could not reasonably anticipate and which it did not address in its motion *in limine*. Allowing Mylan to file the reply brief attached as Exhibit A hereto will allow the Court the opportunity to have a full understanding of the facts and law. Allowing the reply brief to be filed will also prevent Plaintiffs from depriving Mylan of an opportunity to address their erroneous and surprising claims.

Mylan’s motion *in limine* was directed to a surprising position taken by Biogen in the December 2019 trial in the related proceedings in Delaware. There Biogen sought to exclude, as prior art, references to a Phase II clinical trial led by Dr. Ludwig Kappos (“Kappos Phase II

<sup>1</sup> Plaintiffs Biogen International GMBH and Biogen MA Inc. are collectively referred to as “Biogen.”

trial”) on the theory that the reference was the sole work of the inventor, Gilmore O’Neill, and published within one year of the alleged priority date. *See* ECF No. 314 at 1. In its response brief (Dkt. No. 314) Biogen made the surprising and erroneous legal claims that (1) Mylan had the burden of establishing that the asserted references are prior art and (2) that the burden of proof excuses the failure of Biogen to disclose the theory. Dkt. No. 314 at 1-2. Biogen also made the surprising and misleading factual claims as to the status of Dr. O’Neill as the “key drafter and planner” of the Kappos Phase II trial, without recognizing the legal obligation to show that the Dr. O’Neill was the *only* drafter. Dkt. No. 314 at 2.

As the attached proposed reply brief shows, the claims of Biogen are in error. A party seeking to rely on the “own work” exception bears the burden of proof, and the burden of proof would not in any case justify the failure to comply with ordinary discovery. Moreover, Biogen does not show that Dr. O’Neill was the only author of the study. Allowing Mylan to address these issues in the attached reply will assist the Court in an accurate ruling and serve the ends of justice. Defendant Mylan Pharmaceuticals Inc. therefore respectfully requests leave to file the attached reply brief.

Respectfully submitted this 21<sup>st</sup> day of January 2019.

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**CERTIFICATE OF SERVICE**

I hereby certify that on the 21st day of January 2020, served the foregoing  
“DEFENDANT’S MOTION FOR LEAVE TO FILE REPLY IN SUPPORT OF MOTION IN  
LIMINE TO EXCLUDE UNDISCLOSED INVALIDITY THEORY (DKT. NO. 301)” with all  
attachments thereto the on the following counsel of record via email:

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